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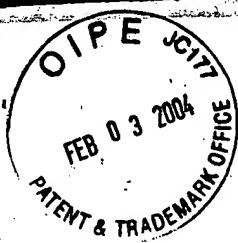
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/671,757 06/28/96 SUERBAUM

S 2356.0073

EXAMINER

HM22/0410

TURNER, S

ART UNIT

PAPER NUMBER

1647

DATE MAILED:

04/10/01

24

Please find below and/or attached an Office communication concerning this application or proceeding.

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APR 19 2001

FINNEGAN, HENDERSON,  
FARABOW, GATES & CALLERI, LLP

Docketed 04/19/01 Attorney KJM/SM  
Case 02356.0073  
Due Date 07/10/01 w/EXT  
Action FINAL RESPONSE DUE  
By AS 1-1-01

U S Patent and Trademark Office  
FEB 03 2004  
Office Action Summary

Application No. 08/671,757	Applicant(s) Suerbaum	
	Examiner Sharon L. Turner, Ph.D.	Group Art Unit 1647

Responsive to communication(s) filed on 1-25-01

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claim**

Claim(s) 10-28, 30, 48, and 52-66 is/are pending in the application

Of the above, claim(s) 10-28, 30, and 48 is/are withdrawn from consideration

Claim(s) 52-55, 60-63, and 65 is/are allowed.

Claim(s) 56-59 and 66 and 64 is/are rejected.

Claim(s) is/are objected to.

Claims 10-28, 30, 48, and 52-66 are subject to restriction or election requirement.

**Application Papers**

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on is/are objected to by the Examiner.

The proposed drawing correction, filed on is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

Application/Control Number: 08671757

Art Unit: 1647

*Response to Amendment*

1. The Art Unit of U.S. Patent application SN 08/671,757 has changed. In order to expedite the correlation of papers with the application please direct all future correspondence to Technology Center 1600, Art Unit 1647, Examiner Turner.
2. The responses filed 11-9-00, 11-15-00 and 1-25-01 with declaration have been entered into the record and fully considered.
3. Claims 10-28, 30, 48 and 52-66 are pending.
4. Newly amended claim 48 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 48 as amended is drawn to a protein which falls into Group II as per the Restriction/Election requirement, Paper No. 5, mailed 10-29-97.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 48 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

5. Claims 10-28, 30 and 48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 7.
6. Any rejection not found herein has been withdrawn by the Examiner.

*New Rejections Based on Amendment*

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**Claim Rejections - 35 USC § 112**

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention:

8. Claims 64 and 66(g) are rejected under 35 U.S.C. 112, first paragraph, for the same reasons of record as set forth in Paper No. 18, mailed 8-9-00 as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 64 and 66(g) remain drawn to a gene where no gene is described by the specification including upstream and downstream non-coding sequences. The examiner suggests amendment away from the terminology of "a gene" towards either "a cassette" as recited in claim 65 or "a polynucleotide sequence encoding".

9. Claims 56-59 and 66(c-d) are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims recite a polynucleotide defined by the restriction sites in Figure 1B. While the claims are read in light of the specification, the specification may not be read into the claims.

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Thus, applicant should recite the specific restriction sites to which they are referring. However, it is noted by the examiner that such description does not lead the skilled artisan to the nucleic acids claimed. In order to do so it appears that the artisan would need access to the clones identified in Figure 1B but which are not limitations of instant claims. A deposit would be required to ensure access to such material. Only then could restriction enzymes provide the skilled artisan access to the recited probes. In the alternative, applicant could possibly delineate the residues of SEQ ID No:3 or 6 which were intended to be encompassed by the restriction sites. The nucleotides intended to be encompassed must be clearly delineated by reference. Finally, the examiner notes that applicant should point to the specification to provide support for such recitations to avoid a new matter rejection. As the nucleic acids at this time cannot be discerned by the examiner, no meaningful search has been conducted for the nucleic acids of claims 56-59 and 66(c-d).

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 56-59 and 66(c-d) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite a polynucleotide defined by the restriction sites in Figure 1B. While the claims are read in light of the specification, the specification may not be read into the claims.

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The examiner cannot discern the structural characteristics of the polynucleotides encompassed by the claims as it is unclear to the examiner what sequences and restriction sites applicant is referring to. The metes and bounds of the claim are indefinite and no meaningful search of the nucleic acids has been conducted.

**Status of Claims**

12. Claims 52-55, 60-63, 65 are allowed.

**Conclusion**

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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Papers relating to this application may be submitted to Technology Center 1600, Group 1645 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1645 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.  
April 6, 2001

*Gary L. Kunz*  
GARY L. KUNZ  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600



PATENT

Attorney Docket No. 02356.0073

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

For: CLONING AND CHARACTERIZATION OF THE *flba* GENE  
OF *H. PYLORI*, PRODUCTION OF AFLAGELLATE STRAINS

Assistant Commissioner of Patents  
Washington, D.C. 20231

Sir:

DECLARATION PURSUANT TO 37 C.F.R. §1.132

I, Agnés Labigne DO HEREBY DECLARE AND SAY:

1. I am one of the joint inventors of the subject matter disclosed in U.S. patent application Serial No. 08/671,757.
2. Attached hereto as Exhibit A are claims 52-66.
3. On information and belief, claims 52-66 of Exhibit A are pending in U.S. patent application Serial No. 08/671,757.
4. I have examined claims 52-66 of Exhibit A and I believe that I am a joint inventor of the subject matter of these claims.
5. I am a coauthor of an abstract identified as Suerbaum et al., "Cloning, Sequencing, and Mutagenesis of the *H. pylori* flbA Gene - a Homolog of the lcrD/flbF/invA Family of Genes Associated with Motility and Virulence," a copy of which is

attached hereto as Exhibit B, and which is hereinafter referred to as the "Suerbaum abstract".

6. I am a joint inventor of the subject matter disclosed in the Suerbaum abstract.

7. On information and belief, the Suerbaum abstract has been cited against claims 52-66 in U.S. patent application Serial No. 08/671,757 because A. Schmitz and C. Josenhans are named as coauthors of the Suerbaum abstract, but are not named as coinventors in U.S. patent application Serial No. 08/671,757, and based on these circumstances, the U.S. Patent Examiner asserted that the subject matter disclosed in U.S. patent application Serial No. 08/671,757 and the subject matter claimed in claims 52-66 in Exhibit A was not invented by the inventors named in the application.

8. The experimental work described in the Suerbaum abstract was conducted by Sebastian Suerbaum, or Agnés Labigne, or performed under our direction or supervision.

9. A. Schmitz and C. Josenhans worked under our supervision. Under our instructions, A. Schmitz rendered technical assistance in sequence analysis and C. Josenhans rendered technical assistance with immunoblot experiments. A. Schmitz and C. Josenhans were rewarded for their work by being included as coauthors of the Suerbaum abstract.

10. A. Schmitz and C. Josenhans did not make an inventive contribution to the experimental work described in the Suerbaum abstract, or an inventive contribution to the subject matter disclosed in U.S. patent application Serial No. 08/671,757, or an inventive contribution to the subject matter of claims 52-66 of Exhibit A, and A. Schmitz and C. Josenhans are not joint inventors of this subject matter.

11. The undersigned declares further that all statements made herein of her own knowledge are true and that all statements made on information and belief are believed to be true and further that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patents issuing therefrom.

Signed at Paris, France  
this 8 day of January, 2001

Agnès Labigne  
Agnès Labigne